

REMARKS/ARGUMENTS

Claims 1-4 and 9-16 are pending. Claims 5-8 have been cancelled. Claims 1, 2, 4 and 9-13 have been amended. Support for the amendment can be found at least at paragraphs [0051] and [0052]. Thus no new matter has been added with this amendment. Reconsideration of this Application and entry of this Amendment is respectfully requested.

Claim Objections

Claims 1 and 4 were objected to for reciting “chordate” instead of “chordae.” Claims 1 and 4 have been amended to recite “chordae” and this to correct this inadvertent error. The Applicants request the withdrawal of the objection to claims 1 and 4.

35 U.S.C. §112 Rejections

Claim 2 was rejected under 35 U.S.C. §112 second paragraph for reciting trademarks, rendering the claims indefinite. Claim 2 recites two cobalt based alloys, an MP35N® alloy, an Elgiloy® alloy. Claim 2 has been amended to delete these trademarks and for no other reason. The Applicant retains the right to claim cobalt based alloys and their equivalents. Withdrawal of the rejection of claim 2 under 35 U.S.C. §112 second paragraph is requested.

35 U.S.C. §102 Rejections

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant the §102 rejections, the cited references must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the cited references fail to do so.

A. Claims 1-4 and 7 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Pub. No. 20020035361 to Houser et al., (the Houser publication).

This rejection is traversed. The Applicant respectfully asserts that the Houser publication fails to include each and every element of the Applicant’s invention as claimed, as required to maintain a rejection under 35 U.S.C. §102(b). *See* MPEP 2131. The Applicant asserts that the Houser publication fails to disclose, teach, or suggest

1) a girdle for surrounding a plurality of chordae tendinae comprising a filamentous body comprising a shape memory material to allow a transition between a linear delivery configuration and an annular treatment configuration, wherein in the annular treatment configuration the filamentous body comprises an inner diameter having a size to contact the plurality of chordae tendinae and to draw the plurality of chordae tendinae closer together to form a bundle of shortened chordate tendinae, as recited in claim 1; and

2) a system for treating a heart valve comprising an elongate delivery catheter having a lumen; and a girdle having an annular treatment configuration sized and shaped to surround a plurality of chordae tendinae of the heart valve and to draw the plurality of chordae tendinae closer together to form a bundle of effectively shortened chordae tendinae, the girdle having a linear delivery configuration sized and shaped to be releaseably disposed within the lumen of the delivery catheter wherein the girdle comprises an elongate body having first and second ends; and a locking mechanism for locking the girdle in the annular treatment configuration, as recited in claim 4.

The Houser publication teaches various devices for treating valvular disease. However, the Houser publication does not teach the device for treating a heart valve claimed by the Applicant in as complete a detail as required to sustain this rejection. The Office action cites to paragraph [111] (reproduced below) of Houser for teaching the claimed device. Paragraph [111] provides in part:

Referring to FIGS. 21A and 21B, apparatus 300 comprises catheter 302 and end effector 304. End effector 304 comprises mechanical reconfigurer 306, adapted to mechanically alter the length of a longitudinal member, for example, chordae tendinae. Reconfigurer 306 comprises a preshaped spring fabricated from a shape memory alloy, for example, nitinol, spring steel, or any other suitably elastic and strong material. Reconfigurer 306 is preshaped such that there is no straight path through its loops. Overlap between adjacent loops is preferably minimized. The shape of reconfigurer 306 causes longitudinal members, such as chordae tendinae, passed therethrough to assume a zig-zag configuration and thereby be reduced in effective length.

At most, the Houser publication teaches a mechanical reconfigurer 306 for mechanically altering the length of a longitudinal member such that the longitudinal member assumes a zig-zag configuration within the loops of the reconfigure 306. In the Response to Arguments section of the current office action it is argued that the device in Houser is capable of surrounding a

plurality of chordae tendinae as claimed. However, to do so would destroy the principle operation of the Houser device. In Houser, the device works by forcing a single chordae tendinae through the loops of the device and into a zig-zag pattern to shorten the chordae tendinae. In the proposed modification suggested in the current office action, none of the plurality of chordae would assume the desired zig-zag pattern as will be appreciated by one with skill in the art. For at least these reasons, independent claim 1 is not anticipated by the Houser publication.

Regarding claim 4, the Houser publication does not teach or suggest a system wherein the girdle comprises an elongate body having first and second ends; and a locking mechanism for locking the girdle in the annular treatment configuration, as claimed by the Applicant. Nowhere within Houser does it teach that the ends of the reconfigure are locked together around a plurality of chordae. For at least this reason, Houser does not anticipate claim 4.

Claims 2 and 3 depend from independent claim 1 and add further features to that claim. For at least this reason claims 2 and 3 are not anticipated by the Houser publication. Claim 7 has been cancelled. For these reasons, the withdrawal of the rejection of claims 1-4 and 7 under 35 U.S.C. § 102(b) is respectfully requested.

B. Claims 1-7 and 13-16 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,629,534 to St. Goar et al., (the St. Goar patent).

This rejection is respectfully traversed. The Applicant asserts that the St. Goar patent fails to include each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §102(e). *See* MPEP 2131. The Applicant asserts that the St. Goar patent fails to disclose, teach, or suggest:

1) a girdle for surrounding a plurality of chordae tendinae comprising a filamentous body comprising a shape memory material to allow a transition between a linear delivery configuration and an annular treatment configuration, wherein in the annular treatment configuration the filamentous body comprises an inner diameter having a size to contact the plurality of chordae tendinae and to draw the plurality of chordae tendinae closer together to form a bundle of shortened chordate tendinae, as recited in claim 1;

2) a system for treating a heart valve comprising an elongate delivery catheter having a lumen; and a girdle having an annular treatment configuration sized and shaped to surround a

plurality of chordae tendinae of the heart valve and to draw the plurality of chordae tendinae closer together to form a bundle of effectively shortened chordae tendinae, the girdle having a linear delivery configuration sized and shaped to be releaseably disposed within the lumen of the delivery catheter wherein the girdle comprises an elongate body having first and second ends; and a locking mechanism for locking the girdle in the annular treatment configuration, as recited in claim 4; and

3) a method for treating a heart valve comprising delivering a girdle in a lumen of a catheter adjacent the heart valve, the girdle having a locking mechanism; releasing the girdle; encircling a plurality of chordae tendinae of the heart valve with the girdle; and locking the girdle into a treatment configuration, as recited in claim 13.

The St. Goar patent teaches a heat treated coil assembly 130 that assumes a stacked helical coil shape about the chordae (see, col. 27 lines 49-59 and FIGS. 39A to 40). Therefore, the St. Goar patent does not teach an annular treatment configuration. The St. Goar patent also does not teach a girdle having a locking mechanism. As such the St. Goar patent does not teach a method of treating a heart valve that includes the limitation of locking the girdle into a treatment configuration. For at least these reasons, independent claim s4 and 13 are not anticipated by the St. Goar patent.

Claims 2 and 3 depend from independent claim 1 and add further features to that claim. For at least this reason claims 2 and 3 are not anticipated by the St. Goar patent. Claims 5-7 have been cancelled. Claims 14-16 depend from independent claim 13 and add further features to that claim. For at least this reason claims 14-16 are not anticipated by the St. Goar patent. For these reasons, the withdrawal of the rejection of claims 1-7 and 13-16 under 35 U.S.C. § 102(e) is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

- C. Claims 8, 9, 11 and 12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Houser '361 or St. Goar in view of US 2002/0173808 to Houser et al., (Houser '808)

This rejection is traversed. As stated above in sections A and B, neither Houser '361 or St. Goar teach all of the limitations of independent claim 4. Houser '808 does not cure these defects.

Claims 9, 11 and 12 depend from independent claim 4 and include all of the elements and limitations of independent claim 4 and, thus, are allowable for at least the same reasons as those stated above for claim 4. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Claim 8 has been cancelled. Applicants, therefore, request the withdrawal of the rejection of dependent claims 8, 9, 11 and 12 under § 103(a).

- D. Claim 10 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Houser '361 or St. Goar in view of Houser '808 and in further view of US 2003/0033006 to Phillips (the Phillips publication)

This rejection is traversed. As stated above in sections A, B and C, neither Houser '361 or St. Goar in view of Houser '808 teach all of the limitations of independent claim 4. Phillips does not cure these defects.

Claim 10 depends from independent claim 4 and includes all of the elements and limitations of independent claim 4 and, thus, is allowable for at least the same reasons as those stated above for claim 4. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claim 10 under § 103(a).

CONCLUSION

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484.

Respectfully submitted,

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